JUL 16 2004

APEC
Asphalt Paving Environmental Council

ASPHALT INSTITUTE
Research Park Drive
P.O. Box 14052
Lexington, KY 40502
Phone 606/288-4960
Fax 606/288-4999
www.asphaltinstitute.org

NAPA
National Asphalt Pavement Association
5100 Forbes Blvd.
Lanham, MD 20706
Phone 301/731-4748
Fax 301/731-4621
www.hotmix.org

S A P A E

The asphalt pavement industry coalition for a better environment through scientific and education programs.

July 16, 2004

Via E-Mail and First-Class Mail

C. W. Jameson, Ph.D.
National Toxicology Program, Report on Carcinogens
79 Alexander Drive
Building 4401, Room 3118
P.O. Box 12233
Research Triangle Park, NC 27709
e-mail: *jameson@niehs.nih.gov*

Re: Comments on the Nomination of Asphalt Fumes for Listing in the NTP Report on Carcinogens, 69 Fed. Reg. 28941 (May 19, 2004)

Dear Dr. Jameson:

The Asphalt Paving Environmental Council welcomes the opportunity to submit comments on the nomination of asphalt fumes for listing in the National Toxicology Program's Report on Carcinogens, 12th Edition. The Asphalt Paving Environmental Council's (APEC) membership includes the National Asphalt Pavement Association (NAPA), the Asphalt Institute (AI), and the State Asphalt Pavement Associations (SAPA). APEC is the asphalt pavement industry coalition for a better environment through scientific research and education programs.

NAPA is the national trade association exclusively representing contractors and related organizations engaged in the production and placement of Hot Mix Asphalt pavements in the U.S. NAPA has about 1100 member companies. The 35 affiliated state asphalt pavement associations represent the interests of the Hot Mix Asphalt Industry and our Members at the state level.

The Asphalt Institute is a U.S.-based association of international petroleum asphalt producers, manufacturers, and affiliated businesses.

APEC has been involved since 1997 in a cooperative relationship with the Laborers' Health and Safety Fund of North America and the International Union of Operating Engineers, unions representing substantial numbers of workers engaged in asphalt paving operations. This broad asphalt fumes partnership includes NIOSH, OSHA, FHWA, and the Association of Equipment Manufacturers (AEM). It was formed both to design and conduct research, and to design and implement steps to protect worker health. This partnership has engaged in a joint effort for a number of years leading to the development and publication of *Engineering Controls on Highway Class Pavers* (NIOSH, 1997) to reduce worker exposure to asphalt fume. Under a unique, voluntary Agreement between OSHA and the manufacturers, all highway class pavers manufactured since July 1, 1997 are equipped with these controls.

The asphalt partnership is also engaged in an ongoing research effort with NIOSH relating to irritation studies, the feasibility of a U.S. Epidemiology Study of Asphalt Paving Workers and, an ongoing evaluation of the effectiveness of the Engineering Controls on Highway Class Pavers. The Harvard School of Public Health is also associated with the Partnership in the EPI feasibility study, and the Partnership has also cooperated extensively with Harvard in a number of ongoing studies involving asphalt paving workers and fumes exposures.

Because the nomination of asphalt fumes for listing [Shelp 2001] was submitted almost three years ago, the purpose of our comments is to ensure that NTP is aware of ongoing scientific studies that are designed to fill major gaps in the existing epidemiological and toxicological data on the potential carcinogenicity of asphalt fumes.

For the reasons described in this letter, APEC strongly urges the NTP to defer consideration of listing of Asphalt Fumes until such time as there are significant results from the extensive research on asphalt fumes that is currently underway in the U.S. and Europe. In the future, the results of this research may suggest to NTP that a listing of Asphalt Fumes is warranted. However, for the reasons described in this submission to you, we do not believe that it would be appropriate for the NTP to undertake a listing at this time.

Background

As you know, NTP last reviewed asphalt fumes in the late 1990s [NTP 1997, 1998], when its Interagency Committee for Chemical Evaluation and Coordination (ICCEC) recommended new research on the basis of NIOSH's nomination for comprehensive toxicological testing [NIOSH 1997a, b]. The Nomination concluded that because of confounding exposures and poor exposure information, the available epidemiologic studies are insufficient to make a reliable judgment with respect to asphalt [NIOSH 1997b]. On the subject of the animal data, the Nomination pointed to the need to determine whether the laboratory-generated asphalt fumes tested in NIOSH skin-painting studies [Thayer 1981, Niemeier 1988, Sivak 1989] are, or are not, representative of workplace exposures [NIOSH 1997a]. The Nomination also noted that "no significant animal inhalation studies to evaluate the risk for cancer have been reported" [NIOSH 1997a].

NTP's Board of Scientific Counselors approved, and its Executive Committee directed, additional research based on the ICCEC recommendation and the NIOSH Research Nomination [NTP 1999]. NIOSH researchers have responded with several new findings [Ma 2002, 2003, 2003; Wang 2001]. Importantly, two major studies that are intended to address the major epidemiological and toxicological data gaps are now underway. These are described briefly below.

The IARC Case-Control Study of European Asphalt Workers

IARC is currently conducting a large multi-country study of European asphalt workers that was initiated after IARC found the available human data to be insufficient for an evaluation of the potential carcinogenicity of asphalt fumes and determined that

the proposed epidemiological study was feasible [Partanen 1994, 1995]. The first phase of the project, a retrospective cohort study of almost 30,000 European asphalt workers, was completed in 2001 [Boffetta 2001, 2003a, b]. The IARC investigators found a small increase in SMRs for lung cancer but, because of the likelihood of confounding due to coal tar exposures and tobacco use, were unable to determine a causal link between exposure to asphalt fumes and risk of cancer [Boffetta 2003b]. They recommended a follow-up nested case-control study of the lung cancer risk in the cohort with individual data on exposures to asphalt and several confounders [Boffetta 2003a]. Approximately one year after the IARC Cohort Study was completed, Watkins, et al. reported on a study of U.S. asphalt roofing manufacturing and asphalt production workers, which found no apparent dose-response relationship between asphalt fumes and lung cancer when individual exposure data were evaluated [Watkins 2002].

The protocol for the IARC Case-Control Study has been finalized and approved, and the Study is fully funded and will begin this summer, 2004. The Study will collect more detailed information on occupational and non-occupational factors for all cohort members who died from, or were diagnosed with, lung cancer (the cases) and a sample of cohort members, matched by date of birth and country, who were free from lung cancer (the controls). The main hypothesis to be tested is whether the risk of lung cancer is increased according to estimated exposure to asphalt fumes, coal tar or other agents occurring in some aspects of the asphalt industry, while adjusting for the estimated genotoxic effect of tobacco smoking and exposure to other known and suspected lung carcinogens. The Study is anticipated to be completed in three years.

The Fraunhofer Institute Inhalation Study in Rats

The other principal data gaps identified during NTP's 1997-98 review are being addressed by the ongoing two-year inhalation carcinogenicity bioassay in Wistar rats being conducted by the Fraunhofer Institute of Toxicology and Experimental Medicine in this study, which began in Spring 2003 with the in life portion to be completed less than a year from now. The rats are being exposed by nose-only inhalation to asphalt fume concentrations of 4, 20 and 100 mg/m^3, based on the results of acute and 90-day toxicity studies which were completed prior to the current bioassay research.

The Fraunhofer investigators have devoted considerable effort to developing and validating a laboratory fume generation procedure that is designed to yield fumes representative of worker exposures [Fraunhofer 2003]. We understand these efforts included consultations with NIOSH. As NTP has recognized [NTP 1999], this is a crucial consideration, since various studies have indicated that the laboratory fume condensates tested in the NIOSH skin-painting studies are markedly different in composition and potential biological activity from asphalt fumes generated under field conditions [Kriech 1999, Kurek 1999, McCarthy 1999]. These concerns have taken on greater weight as a result of subsequent studies indicating that field fumes generated in U.S. asphalt paving and roofing operations appear to have even lower potential for carcinogenic effects than the non-active fractions of the NIOSH laboratory fume condensates [Kriech 2002, 2004].

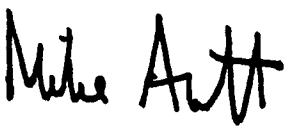
Community Concerns

The impetus for this nomination appears to have been initiated by an issue associated with a local HMA plant location. NAPA and its partners have worked very closely with EPA & State Agencies to address these concerns. NAPA, as an organization, sponsors a continuous improvement effort through its Diamond Achievement Commendation for Excellence in Hot Mix Asphalt Plant/Site Operations. This voluntary self-assessment activity is specifically targeted to maintaining and improving contractor community relationships, including environmental protection, and the safety and health of those in the community as well as employees engaged in paving activities. The categories of review include appearance, operations, environmental practices, safety practices, permitting and regulatory compliance, and most important, community relations. Nationwide, nearly 500 HMA Plants have achieved Diamond status.

Conclusion

During the period since NTP last evaluated the data on asphalt fumes, no major studies have been reported that change fundamentally the conclusion that additional data are needed for a scientifically sound evaluation of the potential carcinogenicity of asphalt fumes. Subsequent authoritative reviews by ACGIH [2000, 2001], NIOSH [2000], Cal/OSHA [2003], and the WHO's International Programme on Chemical Safety [CICAD 2004] are all consistent with the NIOSH Research Nomination that NTP acted-on in 1997-98. The ongoing IARC and Fraunhofer studies directly address the primary data gaps identified at that time and are expected to be completed in the next several years. In light of these facts, we respectfully request that the NTP defer its review of asphalt fumes for listing in the RoC pending the completion of the ongoing studies.

Sincerely,



Peter T. Grass, P.E.
President
Asphalt Institute

Mike Acott
President
National Asphalt Pavement Association

References

ACGIH 2000. American Conference of Governmental Industrial Hygienists, 2000 TLVs® and BEIs®: Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices. Cincinnati OH: ACGIH, 2000.

ACGIH 2001. TLV® Committee, Asphalt (Bitumen) Fumes. Documentation; Cincinnati OH: ACGIH 2001.

Boffetta 2001. Boffetta P, Burstyn I, Partanen T, Kromhout H, Svane O, Langard S, Jarvholm B, Frentzel-Beyme R, Kauppinen T, Stucker I, Shaham J, Heederik D, Ahrens W, Bergdahl I, Cenee S, Ferro G, Heikkila P, Hooiveld M, Johansen C, Randem B, Schill W, *IARC Epidemiological Study Of Cancer Mortality Among European Asphalt Workers*. IARC, Lyon, France: IARC, Internal Report No. 01/003, October 2001.

Boffetta 2003a. Boffetta P, Burstyn I, Partanen T, Kromhout H, Svane O, Langard S, Jarvholm B, Frentzel-Beyme R, Kauppinen T, Stucker I, Shaham J, Heederik D, Ahrens W, Bergdahl I, Cenee S, Ferro G, Heikkila P, Hooiveld M, Johansen C, Randem BG, Schill W, *Cancer Mortality Among European Asphalt Workers: An International Epidemiological Study. I. Results of the Analysis Based on Job Titles.* Am J Ind Med 2003; 43:18-27.

Boffetta 2003b. Boffetta P, Burstyn I, Partanen T, Kromhout H, Svane O, Langard S, Jarvholm B, Frentzel-Beyme R, Kauppinen T, Stucker I, Shaham J, Heederik D, Ahrens W, Bergdahl I, Cenee S, Ferro G, Heikkila P, Hooiveld M, Johansen C, Randem BG, Schill W, *Cancer Mortality Among European Asphalt Workers: An International Epidemiological Study. II. Exposure to Bitumen Fume and Other Agents.* Am J Ind Med 2003; 43:28-39.

Cal/OSHA 2003. Cal/OSHA Airborne Contaminants Advisory Committee, Draft Minutes: February 14, 2003 Meeting (March 10, 2003).

Fraunhofer 2003. Fraunhofer Institute of Toxicology and Experimental Medicine, Collection, Validation and Generation of Bitumen Fumes for Inhalation Studies on Rats. Hannover, Germany; Final Report (Draft), September 24, 2003.

Kriech 1999. Kriech AJ, Kurek JT, Herbert L, *Effects of Mode of Generation on the Composition of Asphalt Fumes*. PAC 1999; 14–15:179–188.

Kriech 2002. Kriech AJ, Kurek, JT, Wissel HL, Osborn LV, and Blackburn GR, *Evaluation of Worker Exposure to Asphalt Paving Fumes Using Traditional and Nontraditional Techniques.* Am Ind Hyg Assn J 2002; 63:628-635.

Kriech 2004. Kriech AJ, Osborn LV, Trumbore D, Kurek, JT, Wissel HL, Rosinski K, *Evaluation Of Worker Exposure To Asphalt Roofing Fumes: Influence Of Work Practices And Materials.* J Occup Environ Hyg 2004; 1:88-98.

Kurek 1999. Kurek, JT, Kriech AJ, Wissel HL, Osborn LV, and Blackburn GR, *Laboratory Generation and Evaluation of Paving Asphalt Fumes.* Transp Res Rec 1999; 1661:35–40.

Ma 2002. Ma, JYC, Yang, H.-M, Barger, M.W., Barger, P.D. and Zhong, B.-Z. *Alteration of Pulmonary Cytochrome P-450 System: Effects Of Asphalt Fume Condensate Exposure.* J. Tox Envr Hlth, Part A, 65:1247-1260, 2002.

MA 2003. Ma, JYC, Rengasamy, A., Frazer, D., Barger, MW, Hubbs, AF, Battelli, L., and Tombyln, S., *Inhalation Exposure of Rats to Asphalt Fumes Generated at Paving Temperatures Alters Pulmonary Xenobiotic Metabolism Pathways without Lung Injury.* Envr Hlth Persp, Vol. 111, No. 9, July 2003

MA 2003. Ma, C, Wang, J and Luo, J, *Exposure to Asphalt Fume Activator Protein-1 through the Phosphatidylinositol 3-Kinase/Akt Signaling Pathway in Mouse Epidermal Cells. JBC 2003, Vol. 278, No. 45, pp.44265-44272.*

McCarthy 1999. McCarthy, BM, Blackburn GR, Kriech AJ, Kurek JT, Wissel HL, Osborn LV, *Comparison of Field Versus Laboratory Generated Asphalt Fumes.* Transp Res Rec 1999; 1661:54–59.

Niemeier 1988. Niemeier RW, Thayer PS, Menzies KT, Von Thuna P, Moss CE, Burg J. *A comparison of the skin carcinogenicity of condensed roofing asphalt and coal tar pitch fumes.* In: Cooke M, Dennis AJ, eds. POLYNUCLEAR AROMATIC HYDROCARBONS: A DECADE OF PROGRESS. TENTH INTERNATIONAL SYMPOSIUM ON POLYNUCLEAR AROMATIC HYDROCARBONS. Columbus, OH: Battelle Press, pp. 609–647 (1988).

NIOSH 1997a. National Institute for Occupational Safety and Health, *Asphalt Fumes as NIOSH Priority Nomination.* June 23, 1997.

NIOSH 1997b. National Institute for Occupational Safety and Health, *Literature Review of Health Effects Caused by Occupational Exposure to Asphalt Fumes: Interim Review Produced by NIOSH in Support of Nomination to the National Toxicology Program.* July 1997.

NIOSH 2000. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, *Hazard Review: Health Effects of Occupational Exposure to Asphalt.* Cincinnati OH, DHHS (NIOSH) Publication No. 2001-110 (December 2000).

NTP 1997. Department of Health And Human Services, Public Health Service, National Institute of Environmental Health Sciences, *National Toxicology Program, Request for Comments on Chemicals Nominated to the National Toxicology Program (NTP) for Toxicological Studies - Recommendations by the Interagency Committee for Chemical Evaluations and Coordination (ICCEC) for Study, No Studies, or Deferral To Obtain Further Supporting Information.* Federal Register 1997; 62(176):47821-47822.

NTP 1998. Department of Health And Human Services, Public Health Service, National Institute of Environmental Health Sciences, *National Toxicology Program, Board of Scientific Counselors' Meeting.* Federal Register 1998; 63(9):2255-2256.

NTP 1999. National Toxicology Program, Annual Plan for Fiscal Year 1998. Research Triangle Park, NC: National Institute of Environmental Health Sciences, USA.

Partanen 1994. Partanen T, Boffetta P, Cancer in Asphalt Workers and Roofers> Review and Meta-Analysis of Epidemiology Studies. Am J Ind Med 1994; 26:721-740

Partanen 1995. Partanen TJ, Boffetta P, Heikkilä PR, Frentzel-Beyme RR, Heederik D, Hours M, Järvholm BG, Kauppinen TP, Kromhout H, Langard S, Svane OB, Bernstein M, Bertazzi PA, Kogevinas M, Neuberger MA, Pannett B, Sunyer J, *Cancer Risk for European Asphalt Workers.* Scand J Work Environ Health 1995; 21:252-8.

Shelp 2001. Shelp J, *Nomination: Asphalt Fumes (letters and statements).* E-Mail to W. C. Jameson dated September 26, 2001.

Sivak 1989. Sivak A, Menzies K, Beltis K, Worthington J, Ross A, Latta R. *Assessment of the cocarcinogenic/promoting activity of asphalt fumes.* Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, NIOSH No. 200–83–2612, NTIS Publication No. PB–91–110–213 (1989).

Thayer 1981. Thayer PS, Menzies KT, von Thuna PC, *Roofing asphalts, pitch and UVL carcinogenesis.* Cincinnati, OH: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, Division of Biomedical and Behavioral Science, NIOSH No. 210–78–0035 (1981).

Wang 2001. Wang, J., Lewis, DK, Castranova, V., Frazer, DG, Goldsmith, T., Tomblyn, S., Simpson, J., Stone, S., Afshari, A, Siegel, PD, *Characterization of Asphalt Fume Composition under Simulated Road Paving Conditions by GC/MS and Microflow LC/Quadrupole Time-of-Flight MS. Anal. Chem. 2001, 73, 3691-3700.*

Watkins 2002. Watkins DK, Chiazze L, Fryar CD, Fayerweather W, *A Case Control Study of Lung Cancer and Non-Malignant Respiratory Disease among Employees in Asphalt Roofing Manufacturing And Asphalt Production*, J Occup Environ Med 2002; 44:551-558.